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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

CV 08 2562

DAVID HILARY, Plaintiff, vs. GENERAL ELECTRIC COMPANY; GE HEALTHCARE, INC.; GE HEALTHCARE AS; BAYER HEALTHCARE PHARMACEUTICALS, INC. f/k/a/ BERLEX, INC. f/k/a BERLEX LABORATORIES, INC.; BAYER SCHERING PHARMA AG; BAYER AG; MALLINCKRODT, INC.; BRACCO DIAGNOSTICS INC; BRACCO RESEARCH USA, INC.; ALTANA PHARMA AG; and NYCOMED INTERNATIONAL	Case No. _____ COMPLAINT JURY TRIAL DEMAND PVT 1) Strict Products Liability / Defective Manufacturing 2) Strict Products Liability / Design Defect 3) Strict Products Liability / Defect Due to Inadequate Warning 4) Strict Products Liability / Defect Due to Nonconformance with Representations 5) Strict Products Liability / Defect Due to Failure to

COMPLAINT AND JURY DEMAND

MANAGEMENT GmbH, Defendants.	Adequately Test 6) Strict Liability in Tort 7) Negligence - Highest Possible Duty of Care 8) Negligence 9) Breach of Express Warranty 10) Breach of Implied Warranty 11) Fraud/Misrepresentation 12) Negligent Misrepresentation 13) Violation of Business & Professions Code § 17200 14) Violation of Business & Professions Code § 17500

Plaintiff, David Hilary, by and through his counsel, BURG SIMPSON ELDREDGE HERSH & JARDINE, P.C., and for his Complaint against Defendants, alleges as follows:

PARTIES AND JURISDICTION

1. Plaintiff, David Hilary, is a resident and citizen of Santa Clara, California.

2. All events in question in this suit took place in the Northern District of California.

3. Plaintiff alleges an amount in controversy in excess of Seventy Five Thousand Dollars ($75,000.00), exclusive of interest and costs. Defendant General Electric Company is a New York Corporation with its principal place of business at 3135 Easton Turnpike, Fairfield, Connecticut 06431. Defendant General Electric Company is a resident of both New York and Connecticut. Defendant General Electric Company is the parent company of Defendant GE Healthcare AS and GE Healthcare, Inc.

4. Omniscan, one of the products in question in this suit, is identified by General Electric Company in its packaging that it is a product of "GE Healthcare," which is a unit/division of General Electric Company. "GE Healthcare" is

prominently identified on the Omniscan packaging/prescribing information, alongside the "GE" monogram. Omniscan is identified as a trademark of GE Healthcare. "GE" and the GE monogram are trademarks of the General Electric Company. The GE Healthcare website, which includes detailed product information concerning Omniscan, is copyrighted by General Electric Company. General Electric Company does business as GE Healthcare, including the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into United States interstate commerce, the drug Omniscan.

5. At all times relevant, Defendant General Electric Company, and/or its corporate predecessors, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

6. Defendant GE Healthcare AS is a Norwegian corporation with its principal place of business in the Kingdom of Norway. Defendant GE Healthcare AS is a subsidiary of General Electric Company. Omniscan's package insert/prescribing information identifies the putative manufacturer of Omniscan as GE Healthcare AS.

7. At all times relevant, Defendant GE Healthcare AS, and/or its corporate predecessors, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the United States interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

8. Defendant GE Healthcare, Inc. is a Delaware corporation with its principal place of business at 101 Carnegie Center, Princeton, New Jersey. Defendant GE Healthcare, Inc. is a resident and citizen of both Delaware and New Jersey. Defendant GE Healthcare, Inc. is a subsidiary of General Electric

Company. Omniscan's package insert identifies the putative distributor of Omniscan as GE Healthcare, Inc.

9. At all times relevant, Defendant GE Healthcare, Inc., and/or its corporate predecessors, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

10. Upon information and belief and at the relevant times, Omniscan was distributed and sold in the United States by GE Healthcare, Inc. and was manufactured by GE Healthcare AS.

11. Defendants General Electric Company, GE Healthcare, Inc., and GE Healthcare AS will be collectively referred to in this Complaint as the "GE Defendants."

12. Defendant Bayer Healthcare Pharmaceuticals, Inc. f/k/a/ Berlex, Inc. f/k/a Berlex Laboratories, Inc. is a Delaware corporation with its principal place of business at 6 West Belt, Wayne, New Jersey. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a resident and citizen of both Delaware and New Jersey. Defendant Bayer Healthcare Pharmaceuticals, Inc. f/k/a/ Berlex, Inc. f/k/a Berlex Laboratories, Inc. is a division of Bayer AG.

13. On April 4, 2007, Berlex, Inc. f/k/a Berlex Laboratories, Inc. changed its name to Bayer Healthcare Pharmaceuticals, Inc. Therefore, defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporate successor to Berlex, Inc. f/k/a Berlex Laboratories, Inc. and, as such, is obligated for its predecessor's liabilities.

14. At all times relevant, Defendant Bayer Healthcare Pharmaceuticals, Inc., and/or its corporate predecessors, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of commerce, directly and indirectly through third parties or related entities, the prescription drug Magnevist (gadopentetate dimeglumine).

15. Bayer Schering Pharma AG is a foreign company domiciled in Germany.

16. Bayer Schering Pharma AG is a corporate successor to Schering AG. Schering AG was renamed Bayer Schering Pharma AG effective December 29, 2006. At all times relevant, Defendant Bayer Schering Pharma AG f/k/a/ Schering AG and/or its corporate predecessors, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into the stream of commerce, directly and indirectly through third parties or related entities, the prescription drug Magnevist (gadopentetate dimeglumine).

17. Defendant Bayer AG is a company domiciled in Germany and is the parent/holding company of both Bayer Healthcare Pharmaceuticals, Inc. and Bayer Schering Pharma AG.

18. Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer AG, Bayer Schering Pharma AG will be collectively referred to in this Complaint as the "Bayer Defendants."

19. Defendant Bayer Healthcare Pharmaceuticals, Inc. is a corporate successor to Berlex Laboratories, Inc. (Berlex) and, as such, is obligated for its predecessor's liabilities. Berlex was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the prescription drug Magnevist (gadopentetate dimeglumine).

20. At all times relevant, the Bayer Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, and into the State of California, either directly or indirectly through third parties or related entities, the diagnostic agent Magnevist (gadopentetate dimeglumine).

21. Defendant Mallinckrodt, Inc. ("Defendant Mallinckrodt") is a Delaware corporation with its principal place of business at 675 McDonnell Blvd.,

St. Louis, Missouri. Defendant Mallinckrodt is a resident and citizen of both Delaware and Missouri. Defendant Mallinckrodt is a subsidiary of Tyco Healthcare Group LP.

22. At all times relevant, Defendant Mallinckrodt was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agent Optimark.

23. Defendant Bracco Diagnostics Inc. is a Delaware corporation with its principal place of business in Princeton, New Jersey.

24. Upon information and belief, at all times relevant, Defendant Bracco Diagnostics Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

25. Upon information and belief, Defendant Bracco Research USA, Inc. is a Delaware corporation, with its principal place of business in Princeton, New Jersey.

26. Upon information and belief, at all times relevant, Defendant Bracco Research USA, Inc. was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

27. Upon information and belief, Defendant ALTANA Pharma AG is a German company with its principal place of business in Germany. Defendant ALTANA Pharma AG manufactured MultiHance and/or ProHance for Bracco Diagnostics Inc.

28. Upon information and belief, at all times relevant, Defendant ALTANA Pharma AG was engaged in the business of designing, licensing,

manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

29. Defendant Nycomed International Management GmbH ("Nycomed") is a Swiss company domiciled in Switzerland. Defendant Nycomed bought ALTANA Pharma AG in 2006. Defendant Nycomed is corporate successor to ALTANA Pharma AG and, as such, is obligated for its predecessor's liabilities.

30. Defendants Bracco Diagnostics Inc., Bracco Research USA, Inc., ALTANA Pharma AG and Nycomed will be collectively referred to in this Complaint and Jury Demand as the "Bracco Defendants."

31. At all times relevant, the Bracco Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the diagnostic agents MultiHance and ProHance.

32. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

33. This Court has personal jurisdiction over Defendants consistent with the laws of the State of California and the United States Constitution because Defendants caused tortious injury in the State of California by an act or omission outside the State of California by virtue of Defendants' regularly conducted business in the State of California from which they derive substantial revenue.

34. Venue in this district is appropriate under 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in the district as Plaintiff David Hilary was administered the offending contrast dye in this district and suffered injury in this district.

GENERAL ALLEGATIONS

35. Magnevist is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography. It is a patented, proprietary formulation that contains the metal gadolinium which is highly toxic in its free state. Magnevist, the chemical name of which is gadopentetate dimeglumine, was represented by the Bayer Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of cranial and spinal anatomy as well as tumors, lesions, and immediately adjacent areas. Magnevist was further represented by the Bayer Defendants to be superior to two of its competitors (Omniscan and OptiMARK) in its thermodynamic and conditional stability, its low volume of excess chelate, and its ability to prevent the release of gadolinium.

36. Berlex obtained FDA approval of its New Drug Application (App. No. 019596) for Magnevist (gadopentetate dimeglumine) on June 2, 1988.

37. In 2006, Bayer AG, which has its legal domicile in Berlin, completed its acquisition of Schering, AG.. Berlex was a U.S. affiliate of Schering, AG. Bayer AG is a holding company that owns and operates Defendants Bayer Healthcare LLC and Bayer Healthcare Pharmaceuticals, Inc.

38. Magnevist (gadopentetate dimeglumine) is cleared from the body solely by glomerular filtration in the kidneys. As a result, it has a prolonged half-life in patients with renal insufficiency and who, therefore, are at increased risk for adverse health effects in connection with Magnevist (gadopentetate dimeglumine) administration.

39. At all times relevant hereto, the Bayer Defendants knew, or should have known, about the significant health risk of Magnevist (gadopentetate dimeglumine) administration to patients with renal insufficiency including, but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs. The Bayer Defendants knew, or should have known, of the need to prevent the

gadolinium contained in its product from becoming free in the body of humans injected with Magnevist through the use of, among other things, proper design, testing, and manufacturing.

40. At all times relevant hereto, the Bayer Defendants knew, or should have known, that there were safer, alternative designs for paramagnetic contrast agents that would prevent or minimize the risk of gadolinium becoming free in the bodies of humans.

41. Nephrogenic Systemic Fibrosis (NSF), also known as Nephrogenic Fibrosing Dermopathy (NFD), has been reported in medical literature since 2000.

42. It has always been the case that this clinical entity now known as NSF/NFD develops in patients with renal insufficiency who have been given an injection of gadolinium-based contrast agent such as Magnevist (gadopentetate dimeglumine).

43. Magnevist (gadopentetate dimeglumine) is chemically distinct from other gadolinium-based contrast agents in that it more easily permits the release of toxic free gadolinium under expected physiologic conditions in patients with renal insufficiency who received it.

44. At all times relevant hereto, the Bayer Defendants knew, or should have known, that its product, Magnevist, was not reasonably fit, suitable or safe for its intended purpose, and specifically, that it was defective and unsafe for use in patients with renal insufficiency such as the Plaintiff, David Hilary, and knew, or should have known, that the gadolinium contained in its product is highly toxic to humans. Further, at all times relevant hereto, the Bayer Defendants knew, or should have known, about the significant health risk of Magnevist administration to patients with renal insufficiency, including, but not limited to, the risk of toxic gadolinium being released into the bodies of those patients, causing severe physical injury.

45. Omniscan is an injectable paramagnetic contrast agent for magnetic resonance imaging and arteriography. It contains the metal gadolinium which is highly toxic in its free state. Omniscan, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethylamide (gadodiamide), is represented by the GE Defendants to be safely and effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

46. Omniscan is cleared from the body solely by glomerular filtration in the kidneys. As a result, it has a prolonged half-life in patients with renal insufficiency and who, therefore, are at increased risk for adverse health effects in connection with Omniscan administration.

47. Omniscan was originally developed by Salutar, Inc. which then conducted pre-clinical testing with Sterling Winthrop and Daiichi Pharmaceuticals. Salutar was subsequently acquired by Nycomed. In 1994, Nycomed acquired Sterling Winthrop's diagnostic imaging business.

48. In 1997, Nycomed acquired Amersham International plc, and the new company was named Amersham plc, which then held the rights to Omniscan.

49. In 2004, General Electric Company acquired Amersham plc and the rights to Omniscan. At the time of the acquisition, Amersham plc was the ultimate parent company of Amersham Health AS, which manufactured the Omniscan that was distributed and sold in the United States, and Amersham Health Inc., which distributed and sold Omniscan in the United States. In 2006, Amersham Health AS was renamed GE Healthcare AS, and Amersham Health, Inc. was renamed GE Healthcare, Inc.

50. Defendants General Electric Company, GE Healthcare AS, and GE Healthcare, Inc. are corporate successors to Amersham plc and its related entities, and, as such, are obligated for their predecessor's liabilities. Amersham plc, either itself or by and through its subsidiaries, was engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into

United States interstate commerce, directly and indirectly through third parties or related entities, the drug Omniscan.

51. Optimark is an injectable paramagnetic contrast agent used for magnetic resonance imaging and arteriography. It contains the metal gadolinium, which is highly toxic in its free state. Optimark, the chemical name of which is gadolinium diethylenetriamine pentaacetic acid bismethoxyethylamide (gadoversetamide), is represented by the Defendant Mallinckrodt to be safely and effectively indicated for intravenous administration to facilitate the visualization of lesions with abnormal vascularity.

52. MultiHance and ProHance are injectable paramagnetic contrast agents for magnetic resonance imaging and arteriography. They contain the metal gadolinium, which is highly toxic in its free state. Upon information and belief, MultiHance and ProHance were represented by the Bracco Defendants to be safely and effectively indicated for intravenous administration to facilitate visualization of lesions with abnormal blood brain barrier or abnormal vascularity of the brain, spine, and associated tissues.

53. At all times relevant hereto, the Defendants knew, or should have known, about the significant health risk of their products' administration to patients with renal insufficiency, including, but not limited to, the risk of nephrogenic fibrosis in the skin and other body organs. At all times relevant hereto, Defendants knew, or should have known, that, in its free state, gadolinium is highly toxic, harmful and dangerous to humans, and causes severe physical injury and knew, or should have known, of the need to prevent the gadolinium contained in its product from becoming free in the body of humans injected with Omniscan, Magnevist, Optimark, and/or, upon information and belief, MultiHance and/or ProHance, through the use of, among other things, proper design, testing, and manufacturing.

54. At all relevant times, Defendants knew, or should have known, that there were safer, alternative designs for paramagnetic contrast agents that would prevent or minimize the risk of gadolinium becoming free in the bodies of humans and knew, or should have known, of safer, alternative designs for imaging systems, like those used by other leading MRI systems manufacturers, that do not use gadolinium based contrast agents, which would provide a safer imaging alternative for the public, including David Hilary.

55. At all times relevant hereto, Defendants knew, or should have known, that their respective products, Omniscan, Magnevist, Optimark and/or upon information and belief, MultiHance and/or ProHance, were not reasonably fit, suitable or safe for their intended purpose and, specifically, that they were defective and unsafe for use in patients with renal insufficiency, such as David Hilary, and knew, or should have known, that the gadolinium contained in its product is highly toxic to humans, and knew, or should have known, about the significant health risk of administration of these products to patients with renal insufficiency, including, but not limited to, the risk of toxic gadolinium being released into the bodies of those patients, causing severe physical injury.

56. David Hilary was exposed to the gadolinium containing contrast dyes Omniscan and upon information and belief, Magnevist, Optimark, ProHance and/or MultiHance, during imaging procedures at Santa Clara Regional Medical Center in 2003 and 2004.

57. After being administered Omniscan and, upon information and belief, Magnevist, Optimark, MultiHance and/or ProHance, gadolinium was released into his body. David Hilary began experiencing symptoms of Nephrogenic Systemic Fibrosis (NSF), also known as Nephrogenic Fibrosing Dermopathy (NFD), after and because of these administrations.

58. NSF/NFD develops only in patients with renal insufficiency, such as David Hilary, who have been given an injection of a gadolinium-based contrast

agent such as Magnevist, Omniscan, Optimark, and/or upon information and belief, MultiHance and/or ProHance.

59. NSF/NFD is predominantly characterized by discoloration, thickening, tightening, and swelling of the skin within weeks after receiving a gadolinium-based contrast injection such as Magnevist, Omniscan, Optimark and/or upon information and belief, MultiHance and/or ProHance. These symptoms can occur weeks or months after a person is administered these dyes. These fibrotic and edematous changes produce muscular weakness and inhibit flexion and extension of joints, resulting in contractures. NSF/NFD often progresses to painful inhibition of the ability to use the arms, legs, hands, feet, and other joints. The skin changes that begin as darkened patches or plaques progress to a "woody" texture and are accompanied by burning, itching, or severe pain in the areas of involvement. NSF/NFD also progresses to a fibrotic or scarring condition of other body organs such as the lungs, heart, liver, and musculature, and that can inhibit their ability to function properly and may lead to death. NSF/NFD is a progressive disease as to which there is no known cure.

60. The GE, Bayer, Mallinckrodt, and upon information and belief, Bracco Defendants consistently failed to warn consumers and/or their health care providers that severe, even fatal, injuries could result when their dyes are administered to patients with renal insufficiency.

61. During the years that the Defendants manufactured, marketed, and sold their respective products, there were numerous case reports, studies, assessments, papers, and other relevant experimental and clinical data that have described and/or demonstrated dissociation and transmetallation in connection with the use of certain gadolinium-based contrast agents. Despite this, the GE, Bayer, Mallinckrodt and, upon information and belief, Bracco Defendants repeatedly failed to adequately revise their package inserts, Material Safety Data Sheets, and

other product-related literature, and to conduct appropriate post-marketing communications in order to convey adequate warnings.

62. The GE, Bayer, Mallinckrodt, and upon information and belief, Bracco Defendants repeatedly and consistently failed to advise consumers and/or their health care providers of the propensity of their products to undergo dissociation and transmetallation in vivo and of the causal relationship between certain gadolinium contrast dye and the development of NSF/NFD in patients with renal insufficiency.

63. David Hilary suffers from debilitating and worsening fibrotic changes to his body as a result of contracting NSF/NFD.

64. As a direct and proximate result of being administered Omniscan and, upon information and belief, Magnevist, Optimark, MultiHance, and/or ProHance, David Hilary suffers serious, progressive, permanent, incurable, and potentially fatal injuries.

65. As a direct and proximate result of being administered Omniscan, and upon information and belief, Magnevist, Optimark, MultiHance, and/or ProHance, David Hilary suffered, and continues to suffer, significant harm, conscious pain and suffering, physical injury, bodily impairment, disfigurement and scarring, including, but not limited to, suffering from NSF/NFD, amputation procedures, and systemic manifestations. David Hilary further suffered and continues to suffer significant mental anguish and emotional distress, physical limitations, pain, injury, damages, and harm. David Hilary has also incurred, and continues to incur, medical expenses and other economic harm as a direct and proximate result of being administered Omniscan, and upon information and belief, Magnevist, Optimark, MultiHance, and/or ProHance.

66. As a direct and proximate result of being administered gadolinium contrast dye, Plaintiff David Hilary has incurred medical expenses, life care expenses, loss of income, loss of past, present and future earning capacity and

other economic harm and has further experienced limited mobility, dramatic life changes, severe and debilitating physical and emotional pain and distress, disfigurement and other non-economic harm.

67. The Defendants, upon information and belief, have, or may have, failed to comply with all federal standards and requirements applicable to the sale of their prescription drugs, Omniscan, Magnevist, Optimark, MultiHance and ProHance, including, but not limited to, one or more of the following violations:

a. The Defendants' prescription drugs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they fail to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. See, 21 U.S.C. §351.

b. The Defendants' prescription drugs are adulterated pursuant to 21 U.S.C. § 351 because, among other things, their strength differs from or their quality or purity falls below the standard set forth in the official compendium for the drugs, and such deviation is not plainly stated on their labels.

c. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because, among other things, their labeling is false or misleading.

d. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for

use, and/or the labeling does not bear adequate warnings against use in those pathological conditions or by children where their use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users.

f. The Defendants' prescription drugs are misbranded pursuant to 21 U.S.C. §352 because they are dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The Defendants' prescription drugs do not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which they are intended, including conditions, purposes, or uses for which they are prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which they are intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendants violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The Defendants' prescription drugs are misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendants violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drugs including degree and rate of absorption, pathways of biotransformation, percentage of dosage as unchanged drug and metabolites, rate or half-time of elimination, concentration in body fluids associated with therapeutic and/or toxic effects, degree of binding to plasma proteins, and/or the degree of update by a particular organ.

k. The Defendants violated 21 CFR § 201.57 because evidence was only available to support the safety and effectiveness of the drugs in selected subgroups of the larger population with a disease, syndrome, or symptom and the labeling failed to describe the available evidence and state the limitations of usefulness of the drugs.

l. The Defendants violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drugs.

m. The Defendants violated 21 CFR § 201.57 because the safety considerations regarding the prescription drugs are such that the drugs should be reserved for certain situations, and the Defendants failed to state such information.

n. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

o. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

p. The Defendants violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drugs and other drugs in the same pharmacologically active and chemically related class.

q. The Defendants violated 21 CFR § 201.57 because the possibility that a patient could develop NSF/NFD is significantly more severe than the other reactions listed in the adverse reactions, and, yet, the Defendants failed to list the development of NSF/NFD before the other adverse reactions on the labeling of the prescription drugs.

r. The Defendants' prescription drugs are mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

s. The Defendants' prescription drugs violate 21 CFR § 210.1 because the process by which they are manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that they meet the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

t. The Defendants' prescription drugs violate 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

u. The Defendants' prescription drugs violate 21 CFR § 211.165 because the test methods employed by the Defendants are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

v. The Defendants' prescription drugs violate 21 CFR § 211.165 in that the prescription drugs fail to meet established standards or specifications and any other relevant quality control criteria.

w. The Defendants' prescription drugs violate 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drugs were not followed.

x. The Defendants' prescription drugs violate 21 CFR § 310.303 in that the prescription drugs are not safe and effective for their intended use.

y. The Defendants violated 21 CFR § 310.303 because the Defendants failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

z. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drugs as soon as possible or at least within 15 days of the initial receipt by the Defendants of the adverse drug experience.

aa. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drugs and evaluating the cause of the adverse event.

bb. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

cc. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek

additional information regarding serious, unexpected adverse drug experiences.

dd. The Defendants violated 21 CFR §§310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report follow-up."

ee. The Defendants violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drugs or otherwise received by the Defendants from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ff. The Defendants violated 21 CFR § 312.32 because they failed to notify the FDA in a written IND safety report of the adverse experiences associated with the use of the prescription drugs that were serious and unexpected.

gg. The Defendants violated 21 CFR § 314.80 by failing to report adverse drug experiences at quarterly intervals for three (3) years from the date of approval of the application, and then at annual intervals.

hh. The Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not

already reported under the post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ii. The Defendants violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

FIRST CAUSE OF ACTION

Strict Products Liability

Defective Manufacturing

68. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

69. The Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

70. The Omniscan, Magnevist, ProHance, MultiHance, and Optimark manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in their manufacture and construction when they left the hands of Defendants in that they deviated from product specifications, posing a serious risk of injury and death.

71. As a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, ProHance, MultiHance, and Optimark as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

72. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of

Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

73. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

74. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

SECOND CAUSE OF ACTION

Strict Products Liability

Design Defect

75. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

76. The Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

77. The Omniscan, Magnevist, ProHance, MultiHance, and Optimark manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective in design or formulation in that, when they left the hands of the Defendants, the foreseeable risks of the products exceeded the benefits associated with their design or formulation, or they were more dangerous than an ordinary consumer would expect.

78. The foreseeable risks associated with the design or formulation of Omniscan, Magnevist, ProHance, MultiHance, and Optimark, include, but are not limited to, the fact that the design or formulation of Omniscan, Magnevist, ProHance, MultiHance, and Optimark is more dangerous than a reasonably prudent

consumer would expect when used in an intended or reasonably foreseeable manner.

79. As a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, ProHance, MultiHance, and Optimark as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

80. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

81. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

82. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

THIRD CAUSE OF ACTION

Strict Products Liability

Defect Due to Inadequate Warning

83. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

84. The Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

85. The Omniscan, Magnevist, ProHance, MultiHance, and Optimark manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective due to inadequate warning or instruction because Defendants knew, or should have known, that these products created significant risks of serious bodily harm and death to consumers, and they failed to adequately warn consumers and/or their health care providers of such risks.

86. The Omniscan, Magnevist, ProHance, MultiHance, and Optimark manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, were defective due to inadequate post-marketing warning or instruction because, after Defendants knew, or should have known, of the risk of serious bodily harm and death from the administration of Omniscan, Magnevist, ProHance, MultiHance, and Optimark, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the products, knowing the products could cause serious injury and death.

87. As a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, ProHance, MultiHance, and Optimark as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

88. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

89. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

90. Defendant's willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

FOURTH CAUSE OF ACTION

Strict Products Liability

Defect Due to Nonconformance with Representations

91. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

92. The Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and made representations regarding the character or quality of Omniscan, Magnevist, ProHance, MultiHance, and Optimark, including representations that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe.

93. The Omniscan, Magnevist, ProHance, MultiHance, and Optimark manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants were defective in that, when they left the hands of Defendants, they did not conform to representations made by Defendants concerning the product.

94. Plaintiff and/or his health care providers justifiably relied upon Defendants' representations regarding the Omniscan, Magnevist, ProHance, MultiHance, and Optimark at the time they were administered to him.

95. As a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, ProHance, MultiHance, and Optimark and the reliance on Defendants' representations regarding the character and quality of Omniscan,

Magnevist, ProHance, MultiHance, and Optimark, he has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

96. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

97. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

98. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

FIFTH CAUSE OF ACTION

Strict Products Liability

Defect Due to Failure to Adequately Test

99. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

100. The Defendants are the manufacturers, designers, distributors, sellers, or suppliers of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

101. Defendants advised consumers and the medical community that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe for use. Defendants failed to adequately test Omniscan, Magnevist, ProHance, MultiHance, and Optimark with respect to their use by consumers with renal insufficiency.

102. Had Defendants adequately tested the safety of Omniscan, Magnevist, ProHance, MultiHance, and Optimark for use by consumers with renal insufficiency and disclosed those results to the medical community or the public, Plaintiff would not have been administered Omniscan, Magnevist, ProHance, MultiHance, or Optimark.

103. As a direct and proximate result of Defendants' failure to adequately test the safety of Omniscan, Magnevist, ProHance, MultiHance, and Optimark, and as a direct and proximate result of Plaintiff being administered Omniscan, Magnevist, ProHance, MultiHance, and Optimark as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

104. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

105. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

106. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

SIXTH CAUSE OF ACTION

Strict Liability in Tort

107. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

108. Defendants used and controlled toxic gadolinium for injection in humans.

109. Gadolinium is highly toxic, inherently dangerous, and ultra-hazardous to humans.

110. Defendants allowed and directed that toxic gadolinium be used and injected in humans.

111. As a direct and proximate result of Defendants' use and control of toxic gadolinium, toxic gadolinium was injected and released into the body of Plaintiff, and he has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm.

112. Defendants are strictly liable for Plaintiff's injuries, damages and losses.

113. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

114. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

115. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

SEVENTH CAUSE OF ACTION

Negligence - Highest Possible Duty of Care

116. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

117. Because gadolinium is highly toxic and inherently dangerous and ultra-hazardous to humans, the Defendants had a duty to exercise the highest possible degree of care in the design, manufacture, testing, sale and/or distribution of their products, Omniscan, Magnevist, ProHance, MultiHance, and Optimark respectively, into the stream of commerce, including the duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

118. Defendants failed to exercise the highest possible degree of care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark into interstate commerce in that Defendants knew, or should have known, that their products were inherently dangerous and ultra-hazardous to humans and caused such significant bodily harm or death and was not safe for administration to consumers.

119. Defendants also failed to exercise the highest possible degree of care in the labeling of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

120. Despite the fact that Defendants knew, or should have known, that Omniscan, Magnevist, ProHance, MultiHance, and Optimark posed a serious risk of bodily harm to consumers and were inherently dangerous and ultra-hazardous to humans and particularly those with renal insufficiency, Defendants continued to manufacture and market Omniscan, Magnevist, ProHance, MultiHance, and Optimark for administration to magnetic resonance imaging and arteriography patients with renal insufficiency.

121. Defendants knew, or should have known, that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise the highest possible degree of care as described above.

122. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

123. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

124. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

125. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

EIGHTH CAUSE OF ACTION

Negligence

126. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

127. The Defendants had a duty to exercise reasonable care in the design, manufacture, testing, sale and/or distribution of their products, Omniscan, Magnevist, ProHance, MultiHance, and Optimark respectively, into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

128. Defendants failed to exercise reasonable care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark into interstate commerce in that Defendants knew, or should have known, that their products caused such significant bodily harm or death and were not safe for administration to consumers.

129. Defendants also failed to exercise ordinary care in the labeling of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and failed to issue to consumers and/or their health care providers adequate warnings of the risk of serious bodily injury or death due to the use of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

130. Despite the fact that Defendants knew, or should have known, that Omniscan, Magnevist, ProHance, MultiHance, and Optimark posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Omniscan, Magnevist, ProHance, MultiHance, and Optimark for administration to magnetic resonance imaging and arteriography patients with renal insufficiency.

131. Defendants knew, or should have known, that consumers, such as Plaintiff, would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

132. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

133. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

134. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

135. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

NINTH CAUSE OF ACTION

Breach of Express Warranty

136. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

137. The Defendants expressly warranted that their products, Omniscan, Magnevist, ProHance, MultiHance, and Optimark respectively, were safe and effective paramagnetic contrast agents for magnetic resonance imaging.

138. The Omniscan, Magnevist, ProHance, MultiHance, and Optimark manufactured and sold by Defendants did not conform to these express

representations because they caused serious injury to consumers when administered in recommended dosages.

139. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

TENTH CAUSE OF ACTION

Breach of Implied Warranty

140. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

141. At the time the Defendants designed, manufactured, marketed, sold, and distributed Omniscan, Magnevist, ProHance, MultiHance, and Optimark respectively, Defendants knew of the use for which Omniscan, Magnevist, ProHance, MultiHance, and Optimark were intended and impliedly warranted their products to be of merchantable quality and safe and fit for such use.

142. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether Omniscan, Magnevist, ProHance, MultiHance, and Optimark were of merchantable quality and safe and fit for their intended use and upon Defendants' implied warranty as to such matters.

143. Contrary to such implied warranty, Omniscan, Magnevist, ProHance, MultiHance, and Optimark were not of merchantable quality or safe or fit for their intended use because the products were unreasonably dangerous as described above.

144. As a direct and proximate result of Defendants' breach of warranty, Plaintiff has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

ELEVENTH CAUSE OF ACTION

Fraud/Misrepresentation

145. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

146. Defendants knowingly and intentionally made material and false and misleading representations to Plaintiff, his physician and to the public that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe for use and that Defendants' labeling, marketing, and promotion fully described all known risks of the products.

147. Defendants' representations were in fact false, as Omniscan, Magnevist, ProHance, MultiHance, and Optimark are not safe for use and their labeling, marketing and promotion did not fully describe all known risks of the products.

148. Defendants had actual knowledge based upon studies, published reports and clinical experience that their products created an unreasonable risk of serious bodily injury and death to consumers, and specifically consumers with renal insufficiency, or should have known such information.

149. Defendants knowingly and intentionally omitted this information in their product labeling, marketing, and promotion and instead, labeled, promoted, and marketed their products as safe for use in order to avoid monetary losses and in order to sustain profits in their sales to consumers.

150. When Defendants made these representations that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, his physician and the public the true facts that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were not safe for use in consumers with renal insufficiency.

151. Defendants had a duty to disclose to Plaintiff, his physician and the public that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were not safe for use in patients with renal insufficiency in that they caused NSF/NFD because they had superior knowledge of these facts that were material to Plaintiff and his physician's decision to use Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

152. Plaintiff and his physician reasonably and justifiably relied on the Defendants' concealment of the true facts and reasonably and justifiably relied upon Defendants' representations to Plaintiff and/or his health care providers that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe for human consumption and/or use and that Defendants' labeling, marketing, and promotion fully described all known risks of the product.

153. Had Plaintiff and his physician known of Defendants' concealment of the true facts that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were not safe for human use, Plaintiff would not have been administered Omniscan or Optimark.

154. As a direct and proximate result of Defendants' misrepresentations and concealment, Plaintiff was administered Omniscan, Magnevist, ProHance, MultiHance, and Optimark and has suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

155. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

156. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

157. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

TWELFTH CAUSE OF ACTION

Negligent Misrepresentation

158. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

159. Defendants, in the course of their business profession, supplied Plaintiff and his physician with false information for guidance in their decision to use Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

160. The false information supplied by Defendants to Plaintiff and his physician was that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe and would not adversely affect Plaintiff's health.

161. In supplying the false information, Defendants failed to exercise reasonable care or competence in obtaining or communicating information to Plaintiff and his physician.

162. The false information obtained and communicated by Defendants to Plaintiff and his physician was material and they justifiably relied in good faith on the information to their detriment.

163. As a result of the negligent misrepresentations of Defendants, Plaintiff suffered injuries, damages and losses as alleged herein.

164. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and

Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

165. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

166. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

THIRTEENTH CAUSE OF ACTION

Violation of Business & Professions Code § 17200

167. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

168. Plaintiff brings this cause of action pursuant to California Business & Professions Code § 17204, in an individual capacity, and not on behalf of the general public. Pursuant to § 17204, Plaintiff is a person who has suffered injury and lost money as a result of Defendants' actions alleged herein.

169. California Business & Professions Code § 17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

170. The acts and practices described above were and are likely to mislead the general public and, therefore, constitute unfair business practices within the meaning of California Business & Professions Code § 17200. The acts of untrue and misleading advertising set forth above are incorporated by reference herein and are, by definition, violations of California Business & Professions Code § 17200. This conduct includes, but is not limited to:

a. Representing to Plaintiff, Plaintiff's physicians and the general public that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe, fit and effective for human consumption, knowing that said representations were false, and concealing from Plaintiff, Plaintiff's physicians and the general public that Omniscan, Magnevist, ProHance, MultiHance, and Optimark had a serious propensity to cause injuries to users and specifically to those users who had renal insufficiency;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that the use of Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe for human use, including use by persons with renal insufficiency, even though Defendants knew this to be false and even though Defendants had no reasonable grounds to believe it to be true;

c. Purposely downplaying and understating the health hazards and risks associated with Omniscan, Magnevist, ProHance, MultiHance, and Optimark; and

d. Issuing promotional literature deceiving potential users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark by concealing material relevant information regarding the safety of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

171. These practices constitute unlawful, unfair and fraudulent business acts or practices within the meaning of California Business & Professions Code § 17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California Business & Professions Code § 17500.

172. The unlawful, unfair and fraudulent business practices of Defendants described above present a continuing threat to members of the public in that Defendants continue to engage in the conduct described herein.

173. As a result of the conduct set forth herein, Defendants have been, and will continue to be, unjustly enriched. Specifically, upon information and belief,

Defendants have been unjustly enriched by receipt of millions of dollars in ill-gotten gains from the sale and prescription of Omniscan, Magnevist, ProHance, MultiHance, and Optimark in California, sold in large part as a result of the acts and omissions described herein.

174. Because of fraudulent misrepresentations made by Defendants as set forth herein and the inherently unfair practice of committing a fraud against the public by intentionally misrepresenting and concealing material information, the acts of Defendants described herein constitute unfair or fraudulent business practices.

175. Plaintiff, pursuant to California Business & Professions Code § 17203, seeks an order from this Court compelling Defendants to provide restitution and to disgorge the monies collected and profits realized by Defendants as a result of their unfair business practices and injunctive relief calling for Defendants to cease unfair business practices in the future.

176. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

177. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

178. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

FOURTEENTH CAUSE OF ACTION

Violation of Business & Professions Code § 17500

179. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

180. Plaintiff brings this cause of action pursuant to California Business & Professions Code § 17500 in an individual capacity and not on behalf of the general public. Pursuant to § 17535, Plaintiff is a person who has suffered injury and lost money as a result of Defendants' actions alleged herein.

181. California Business & Professions Code § 17500 provides that it is unlawful for any person, firm, corporation or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.

182. At all times herein mentioned Defendants have committed acts of disseminating untrue and misleading statements as defined by California Business & Professions Code § 17500 by engaging in the following acts and practices with intent to induce members of the public to purchase and use Omniscan, Magnevist, ProHance, MultiHance, and Optimark:

a. Representing to Plaintiff, Plaintiff's physicians and the general public that Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe, fit and effective for human consumption, knowing that said representations were false, and concealing from Plaintiff, Plaintiff's physicians and the general public that Omniscan, Magnevist, ProHance, MultiHance, and Optimark had a serious propensity to cause injuries to users and specifically to those users who had renal insufficiency;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that the use of Omniscan, Magnevist, ProHance, MultiHance, and Optimark were safe for human use,

including use by persons with renal insufficiency, even though Defendants knew this to be false and even though Defendants had no reasonable grounds to believe it to be true;

c. Purposely downplaying and understating the health hazards and risks associated with Omniscan, Magnevist, ProHance, MultiHance, and Optimark; and

d. Issuing promotional literature deceiving potential users of Omniscan and Optimark by concealing material relevant information regarding the safety of Omniscan and Optimark.

183. The foregoing practices constitute false and misleading advertising within the meaning of California Business & Professions Code § 17500.

184. The acts of untrue and misleading statements by Defendants described herein present a continuing threat to members of the public in that the acts alleged herein are continuous and ongoing, and the public will continue to suffer the harm alleged herein.

185. As a result of the conduct set forth herein, Defendants have been, and will continue to be, unjustly enriched. Specifically, upon information and belief, Defendants have been unjustly enriched by receipt of millions of dollars in ill-gotten gains from the sale of Omniscan, Magnevist, ProHance, MultiHance, and Optimark in California, sold in large part as a result of the acts and omissions described herein.

186. Pursuant to California Business & Professions Code § 17535, Plaintiff seeks an order from this Court compelling Defendants to provide restitution and disgorge the monies collected and profits realized by Defendants as a result of their unfair business practices and injunctive relief calling for Defendant to cease unfair business practices in the future.

187. Plaintiff seeks the imposition of a constructive trust over and restitution and disgorgement of the monies collected and profits realized by

Defendants and for Defendants to cease such false and misleading advertising in the future.

188. The acts, conduct and omissions of Defendants as alleged herein were willful and malicious and were done with a conscious disregard for the rights of Plaintiff and other users of Omniscan, Magnevist, ProHance, MultiHance, and Optimark and for the primary purpose of increasing Defendants' profits from the sale and distribution of Omniscan, Magnevist, ProHance, MultiHance, and Optimark.

189. As a direct and proximate result of Defendants' actions as alleged herein, Plaintiff has suffered injuries, damages and losses as set forth in this complaint.

190. Defendants' willful, malicious, outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against all Defendants in an amount to be determined at a trial of this action.

WHEREFORE, Plaintiff prays for relief as follows:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;
2. Medical expenses and other economic damages in an amount to be determined at trial of this action;
3. Punitive damages in an amount to be determined upon proof at trial;
4. Restitution, disgorgement of profits, and other injunctive and equitable relief;
5. Attorneys' fees, expenses, and costs of this action; and
6. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury on all issues so triable.

DATED: May 20, 2008

KABATECK BROWN KELLNER LLP

By: _____
Richard L. Kellner
Counsel for Plaintiff

BURG SIMPSON ELDREDGE HERSH & JARDINE, P.C.
JOHN M. RESTAINO,

E-filing

FILED

JS 44 (Rev. 12/07) (Cand rev 1-16-08)

CIVIL COVER SHEET

PVT

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON PAGE TWO OF THE FORM.)

I. (a) PLAINTIFFS
DAVID HILARY

DEFENDANTS
GENERAL ELECTRIC COMPANY (See attachment)

(b) County of Residence of First Listed Plaintiff Santa Cruz, CA
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)
Kabateck Brown Kellner LLP
644 South Figueroa Street
Los Angeles, CA 90017
Tel; 213 217-5000

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated or Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury—Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☒ 365 Personal Injury — Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881		☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	PROPERTY RIGHTS	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 820 Copyrights	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 830 Patent	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health	☐ 840 Trademark	☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act		☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		FEDERAL TAX SUITS	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty	IMMIGRATION	☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other	☐ 462 Naturalization Application	☐ 871 IRS—Third Party 26 USC 7609	☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights	☐ 463 Habeas Corpus – Alien Detainee		☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition	☐ 465 Other Immigration Actions		

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
28 USC Sec. 1332
Brief description of cause:
Strict Prod. Liability; Negligence; Breach of Express Warranty; Violation of Bus. & Prof. Code Sec. 17200, 17500

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY PLEASE REFER TO CIVIL L.R. 3-12 CONCERNING REQUIREMENT TO FILE "NOTICE OF RELATED CASE".

IX. DIVISIONAL ASSIGNMENT (CIVIL L.R. 3-2)
(PLACE AND "X" IN ONE BOX ONLY) ☐ SAN FRANCISCO/OAKLAND ☒ SAN JOSE

DATE
May 20, 2008

SIGNATURE OF ATTORNEY OF RECORD

ATTACHMENT

GE HEALTHCARE, INC.; GE HEALTHCARE AS; BAYER HEALTHCARE PHARMACEUTICALS, INC. f/k/a/ BERLEX, INC. f/k/a BERLEX LABORATORIES, INC.; BAYER SCHERING PHARMA AG; BAYER AG; MALLINCKRODT, INC.; BRACCO DIAGNOSTICS INC; BRACCO RESEARCH USA, INC.; ALTANA PHARMA AG; and NYCOMED INTERNATIONAL MANAGEMENT GmbH,